K060807 page 1

ScoutPro 7F
Special 510(k) Premarket Notification

APR 2 4 2006

1. 510(k) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	ScoutPro 7F
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Wire, Guide, Catheters, Percutaneous
Product Code:	DQY, DRE, DQX

General Description:

ScoutPro 7F is a special delivery system for coronary sinus leads. It is designed to assist with introducing leads into the vessels of the left side of the heart via the coronary sinus. The system also facilitates access to the coronary sinus venous system as well as probing the coronary sinus. It is a modified version of BIOTRONIK's current legally marketed predicate device ScoutPro (K033320, 11-19-2003). The following ScoutPro 7F accessories are subject to this Special 510 (k)

The basic set **ScoutPro 7F** contains the following components:

- 1 hemostatic valve
- 2 guiding catheters MPEP and BIO 2
- 1 dilator for the guiding catheter
- 1 peel-away sheath 10F with dilator
- 1 guide wire
- 1 needle
- 1 syringe
- 2 slitter tools 4.9 F and 6.3 F for different lead sizes

ScoutPro 7F Sheath "Hook" contains the following components:

- 1 guiding catheter "Hook"
- 1 dilator for the guiding catheter

ScoutPro 7F Sheath "Multi-Purpose Hook" contains the following components:

- 1 guiding catheter "Multi-Purpose Hook"
- 1 dilator for the guiding catheter

ScoutPro 7F Sheath "Amplatz 6.0" contains the following components:

- 1 guiding catheter "Amplatz 6.0"
- 1 dilator for the guiding catheter

Additionally, the hemostatic valve and the slitter tools are available separately. The hemostatic valve and slitter tool accessories have been cleared with the legally marketed predicate device ScoutPro (K033320, 11-19-2003).

Device Modification:

The main difference between the predicate device ScoutPro and the ScoutPro 7F described in this documentation is the inner diameter of the guiding catheters included in the system. Some other modifications include changes to the accessories like the markings on the hemostatic valve, a larger scaled syringe and a different plastic material for slitter tools.

Predicate Device:

BIOTRONIK proposes the following delivery system cleared through 510(k) notification as a predicate device for the ScoutPro 7F:

- BIOTRONK's ScoutPro (#K033320, 11-19-2003)

Indication for Use:

The intended use of the ScoutPro 7F is for introducing leads into the vessels of the left heart via the coronary sinus.

Name and Address of Manufacturer:	BIOTRONIK GmbH & Co. KG (reg. no. 9610139) Woermannkehre 1, 12359 Berlin, Germany 011-49-30-689-05-1210
Name and Address of Contract Manufacturer:	BIOTRONIK AG (reg. no. 8043892) Ackerstrasse 6 8180 Bülach, Switzerland 011-41-44-864-5169
Contact Person(s) and Phone Number:	Jon Brumbaugh Director, Regulatory Affairs and Compliance Phone (888) 345-0374 Fax (503) 635-9936 jon.brumbaugh@biotronik.com

2. INDICATIONS FOR USE

The intended use of the ScoutPro 7F is for introducing leads into the vessels of the left heart via the coronary sinus.

See **Appendix 1** for the 510(k) Indications for Use Form.

3. CONTRAINDICATIONS

The ScoutPro 7F is contraindicated for:

- Patients with known or possible obstructed coronary sinus vasculature or inadequate coronary sinus anatomy.
- Patients with active systemic infection.

4. DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE PRODUCTS

4.1 DEVICE DESCRIPTION

The ScoutPro 7F delivery system is a modified version of the BIOTRONIK's current legally marketed ScoutPro delivery system (K033320, dated 11-19-2003). The ScoutPro 7F functions similarly to that of a standard introducer for pacemaker leads. It contains catheters with various distal arcs to facilitate and support the implantation of left-ventricular polyurethane leads up to 6.6 F in the coronary venous system.

For implantation of left ventricular pacing leads, the subclavian or the cephalic vein is used as a point of entry into the venous system. After gaining access to the vein, one of the braided, peel-away guiding catheters (long sheaths) used in combination with the dilator and hemostatic valve is introduced into the vein using a guide wire initially positioned in the atrium. Selection of a guiding catheter with a suitable curve (arc) allows the distal tip of the catheter to probe the coronary sinus and facilitates implantation of the lead into the coronary veins. A side access in the hemostatic valve enables the injection of irrigation solutions and contrast dyes to facilitate gaining access to the coronary sinus.

After successful placement of the lead, the hemostatic valve and the guiding catheter are removed over the lead. In this process, the pre-slitted peel-away grip, which is glued to the proximal end of the guiding catheter, is broken off. The catheter is opened along the pre-slit portion (2 cm). Then, using the slitter tool, the guiding catheter is slit from proximal to distal end.

The main difference between the predicate device ScoutPro and the ScoutPro 7F described in this documentation is the inner diameter of the guiding catheters included in the system. Most coronary sinus leads to be implanted have a smaller diameter, for which a 7F introducer system is sufficient. A comparison table with the predicate device ScoutPro is provided in **Section 4.2**.

The basic set **ScoutPro 7F** (Figure 1) contains the following components with changes (if any) listed in Table 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2006

Biotronik, Inc.
c/o Mr. Jon Brumbaugh
Director, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035

Re: K060807
Trade/Device Name: ScoutPro 7F
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 23, 2006
Received: March 24, 2006

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

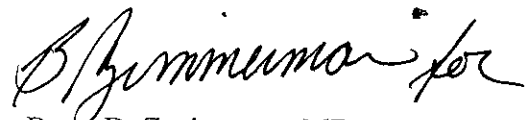
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ScoutPro 7F

Indications for Use:

The intended use of the ScoutPro 7F is for introducing leads into the vessels of the left heart via the coronary sinus.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. Gunnuma
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060807